REMARKS

Claims 30, 31, 32, 44, 45, and 46 have been cancelled. Claims 1-29, 33-43, and 47-53 are now pending in the application. Claims 1, 3, 4, 6, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 27, 33, 34, 35, 36, 37, 40, 41, 42, 43, 47, 48, and 49 have been amended. New claims 50, 51, 52, and 53 have been added. No new matter has been added by amendment. Reexamination and reconsideration of the claims as amended are respectfully requested.

Claim Objections

2. The Examiner objects to claims 8 and 27 for being in improper form because a multiple dependent claim should refer to other claim in the alternative only. Claims 8 and 27 have been amended and are now in proper form.

Claim Rejections – 35 USC § 112, second paragraph

3. The Examiner rejects claims 1-49 under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejects claims 1, 6, 12, 14, 21, 25, 31, 33, 37, 40-42, and 44-46 and the claims that are dependent thereon as indefinite due to the recitation of "PH54M ". The Examiner states that, "Amending claims 1, 6, 21, 25, 37, and 40 to recite the ATCC deposit number in which seed of corn inbred line PH54M has been deposited would overcome the rejection." Claims 1, 6, 21, 25, 37, and 40 have been so amended and the ATCC deposit receipt is attached to this response.

The Examiner rejects claims 3 and 22 for the recitation of "wherein the plant is male sterile". The Applicant traverses the rejection but has amended the claims for clarification purposes and to expedite prosecution. Claim 3 has been amended by replacing "male sterile" with --detasseled– as suggested by the Examiner. The Examiner suggests that a new claim be directed towards a method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 with a nucleic acid that confers male sterility, and another

claim directed toward the male-sterile plant produced by the method of transforming. Claim 22 has been amended and now reads, "The maize plant of claim 2, wherein genes controlling male sterility have been transferred into said maize plant through crossing, wherein PH54M is a recurrent parent, and wherein said maize plant has essentially the same morphology and physiology of inbred maize line PH54M other than the trait of male sterility." Starting on page 1, line 34 and going through line 14 of page 3 of the specification it states that various genes, nuclear and cytoplasmic, have been used to control sterility in maize plants. In the specification on page 4, lines 7-13, it states, "Backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. This can be accomplished, for example, by first crossing a superior inbred (recurrent parent) to a donor inbred (non-recurrent parent), that carries the appropriate gene(s) for the trait in question. The progeny of this cross is then mated back to the superior recurrent parent followed by selection in the resultant progeny for the desired trait to be transferred from the non-recurrent parent." The technique of backcrossing male sterility genes into an inbred maize plant is well known and well understood to one of ordinary skill in the art. The technique has been successively used since the 1950's (see pages 585-586 of Wych, 1988 included in the Information Disclosure Statement). The amendments contain no new matter. The Applicant requests reexamination and reconsideration of the claims as amended.

The Examiner rejects claims 5 and 24 because there is no antecedent basis for "protoplasts". The Applicant has amended claims 4 and 23. The claims now read, "A tissue culture of regenerable cells or protoplasts from the plant of claim 2 {21}." Thus the term "protoplasts" in claims 5 and 24 that depend from claims 4 and 23 respectively, has proper antecedent basis. The amendments place the claims in condition for allowance.

The Examiner rejects claims 14, 33, 41, 45, and 46 because they contain terms such as "high" and "above average" which "do not reasonably apprise one of the scope of the invention." Claims 45 and 46 have been cancelled. Claims 33 and 41 have been amended and no longer include such terms or

traits. Claim 14 has been amended and no longer includes such terms as "high". Claim 14 now reads, "A maize plant, or parts thereof, wherein at least one ancestor of said maize plant is the maize plant of claim 2, said maize plant expressing a combination of at least two PH54M traits which are not significantly different from PH54M traits when determined at a 5% significance level and when grown in the same environmental conditions, said PH54M traits selected from the group consisting of: a relative maturity of 98 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, grain yield, resistance to late season stalk lodging, and resistance to Northern Leaf Blight." Applicant points out that claim 14 has been amended to clearly define the traits of PH54M that could be found in a maize plant produced from PH54M. Applicant has amended the claim using the term "not significantly different from PH54M traits when determined at a 5% significance level..." as a definitive term. In the specification pages 39-56, the tables show mean trait values. The standards against which the listed traits should be compared are the mean values for those traits exhibited by PH54M or a maize plant produced from PH54M in a side-by-side comparison or under other similar environmental conditions. For example, on page 36 lines 2-3 of the specification it discusses that inbred PH54M had significantly lower harvest moisture than inbred PH1W2. Applicant also points out that one of ordinary skill in the art of plant breeding would know how to evaluate the traits of two inbred maize lines to determine if they are not significantly different to a 5% significance level in the expression of a given trait. On pages 275-276 in Principles of Cultivar Development (1987) Fehr writes, "Two or more independent comparisons of lines in a test provide a means of estimating whether variation in performance among lines is due to differences in genetic potential or to environmental variation." A copy of Fehr, pages 261-286, is attached to this Amendment and Request for Reconsideration as Appendix A. As was done by the Applicant in the specification, mean trait values would be used to determine whether the trait differences are significant. Further, the claim, as amended, requires that the traits be measured on plants grown in the same environmental conditions.

The Examiner rejects claims 16 and 35 because of improper antecedent basis and has suggested that the recitation "corn plant breeding program" be replaced with --method--. Claims have been amended as suggested by the Examiner thus placing them in condition for allowance.

The Examiner has rejected claims 19, 20, 48 and 49 for improper antecedent basis. Claims 19, 20, 48 and 49 have been amended and are now in proper form for allowance.

The Examiner rejects claim 40 because of the recitation of the word "comprising". The Examiner states that the claim is indefinite because it "does not clearly indicated how many crosses are to be performed by the method." Claim 40 has been amended to specify the first generation (F1) plant. Dependent claim 41 has also been amended to reflect the change in claim 40.

Claim Rejections – 35 USC § 112, first paragraph

4. The Examiner rejects claims 9-20, 28-39, 41-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant traverses the rejection.

The Examiner rejects claims 9, 10, 28, and 29 that are directed to F1 hybrids produced with PH54M as a parent. Applicant notes that a claim to the F1 hybrid made with a deposited inbred was expressly acknowledged without reservation by the United States Supreme Court In *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 60 USPQ 2d 1865,1873 (S.Ct. 2001), when the Supreme Court wrote, "...a utility patent on an inbred plant line protects the line as well as all hybrids produced by crossing that inbred with another plant line."

Furthermore, one of ordinary skill in the art would know if they were using or one could easily identify if they were using PH54M. All F1 plants would have essentially the same genetic markers as the deposited PH54M. It is well known to anyone skilled in the art that a hybrid has a genome with one set of the alleles from each inbred. Therefore the genetic profile exhibited in the deposit would be

exhibited in the hybrid. As stated in the specification on page 16, lines 8-23, there are many laboratory-based techniques available for the analysis comparison and characterization of plant genotype such as Restriction Length Polymorphisms (RFLPs) and Simple Sequence Repeats (SSRs). Such techniques have been known for some time and may be used to identify whether or not PH54M was used to develop a hybrid. Applicant also submits to the Examiner the journal article by Berry et al. (2002). This article discusses the probability of identifying the parents of the hybrid by SSR data when neither parent is known. A copy of article by Berry et al. is attached to this Amendment and Request for Reconsideration as Appendix B. The results of the experiment showed that using 100 SSR loci markers resulted in correct parental ranking of inbreds for 53 out of 54 hybrids. Applicant also points out that any breeder of ordinary skill in the art will know the identity of both parents used to produce a hybrid.

The Examiner broadly rejects product claims encompassing any modification of PH54M, no matter how minor the modification or routine the modification is for a breeder of ordinary skill in the art to make.

As noted in the specification, the development of an inbred line is a time consuming and labor intensive activity. On average, between 10,000 to 20,000 lines are created and screened in order to develop any maize inbred line for which Applicant files a patent application. Once developed, the inbred line is useful for two purposes: (1) to make commercial hybrids, and (2) as a source of breeding material for the development of new inbreds that retain its desired characteristics. A breeder desiring to make a line with similar traits to PH54M would be greatly advantaged by being able to use PH54M as starting material. This is because the linked genes arranged through Applicant's breeding efforts, and fixed in PH54M, can be maintained in the progeny of PH54M by a breeder of ordinary skill in the art. For example, if a breeder of ordinary skill in the art desired an early maturity version of PH54M, the breeder could cross PH54M to an earlier maturing variety, select for progeny with at least two desired PH54M traits that also express early maturity, and continue selecting for the traits of

PH54M combined with early maturity. Optionally, the breeder could backcross to PH54M to obtain further genetic contribution from PH54M. The end result is the development of an inbred line with substantially all of the benefit of Applicant's work but with only a fraction of the effort.

Specifically, in rejecting the claims for lack of written description, the Examiner states, "the specification also does not describe the plants produced by the corn breeding programs, transgenic PH54M plants, PH54M plants comprising single gene conversion(s), or by crosses wherein at least one ancestor is the corn variety PH54M, other than PH54M/PH7JB. The morphological and physiological traits of the corn plants that are crossed with PH54M, and with progeny of that cross, are unknown, and the description of progeny and descendents of corn plant PH54M are unknown. The description of PH54M is not indicative of the description of plants and seed produced by the breeding programs and crosses, or any of its descendents. The claimed invention also encompasses plants that express at least two of the 'PH54M traits' listed in claims 14, 33, 41, 45, and 46. However, to say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by PH54M. Two plant traits do not provide any description of the other traits of the plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant PH54M. For, example, Loisel et al. (U.S. Patent No. 5,986,185) describes a corn plant, designated 'PH24D,' which has at least two traits in common with PH54M, high grain yield, above average resistance to Northern Leaf Blight, and being adapted to the Northcentral region of the United States, for example (col. 10, lines 52-67; Table 1). The instantly claimed corn plants could have PH24D as an ancestor, as well as PH54M, in which case the high grain yield, resistance to Northern Leaf Blight, and adaptability to the Northcentral region traits, for example, could have been inherited from PH24D. The claims also encompass plants that do not have to express any of the traits that are expressed by PH54M."

Applicant notes that Examiner's comments represent a change of patent office policy. In numerous previous cases involving the protection of germplasm and progeny claims, including cases allowed after the recently adopted written description guidelines, the listing of traits was previously required by the patent office as a way to meet the written description requirement with respect to progeny. One reason for using traits as a means of description is because it was, and still is, technologically impossible to sequence the entire genome of a specific variety.

If it was possible to sequence the genome of a variety, PH54M could be described and compared to the prior art to identify its unique genetic sequences and sequence combinations, and presumably, claims to progeny retaining those unique genetic aspects would be allowed by the patent office. This would be analogous to the way claims are examined for individual short genetic sequences and claims allowed for any plant comprising a specific transgene. Applicant asserts that the fact that technological tools do not exist to fully describe the unique characteristics of the full genome of PH54M does not make the progeny lines derived therefrom any less entitled to adequate patent protection. It is the purpose of the patent law to protect new and useful processes, compositions of matter and improvements thereof. 35USC 101.

This situation is somewhat analogous to Ex Parte Tanksley, 37 USPQ2d. 1382. In that case the Examiner desired that Tanksley claim according to sequence data to "better characterize the cDNA clones" and "facilitate a complete search of the prior art" and issued a 112 first paragraph written description rejection. The Board held that "the section 112 rejection amounts to a requirement...that the appellants amend their claims in a specified manner...We find no language in the statute or case law which would support that requirement." The Board, in treating the section 112 first paragraph rejection as a 112 second paragraph rejection, held that "In our judgement, a patent applicant is entitled to a reasonable degree of latitude in complying with the second paragraph of 35 U.S.C. 112 and the examiner may not dictate the literal terms of the claims for the stated purpose of facilitating a search of the

prior art. Stated another way, a patent applicant must comply with 35 U.S.C. 112, second paragraph, but just how the applicant does so, within reason, is within applicant's discretion." Id. at 1386.

Applicant has amended claims 17, 33 and 36 to limit the progeny covered to those within a pedigree distance of two crosses away from PH54M. Claim 41 is limited to one cross away from PH54M by virtue of dependency. Within the plant breeding arts breeders use pedigree as a means to characterize lines in reference to their progenitors. To those of ordinary skill in the art, this indicates that a line fewer crosses away from a starting line will be, as a whole, more highly related to the starting line. Thus, the work of the original breeder in developing the starting line will be retained in the closely related progeny. More specifically, traits and linkage groups present in PH54M will be retained in progeny that are within 2 outcrosses from PH54M. Applicant submits that characterization of the progeny of PH54M by virtue of their filial relationship is clearly within reason. Not only are filial descriptions used by breeders to evaluate materials for use in their breeding programs, but it is standard practice within the plant breeding industry for licensor's of inbred maize lines to retain a royalty from lines developed through the use of their inbreds. Those royalties are, in almost all cases, based on the filial relationship between the licensed inbred used in breeding and the progeny line commercialized. This provides evidence that those of ordinary skill in the art of plant breeding describe progeny in terms of pedigree.

Applicant also notes that the mere fact that the progeny have not been created does not prevent them from being patented. As stated in MPEP 2163 (3) (a), "An invention may be complete and ready for patenting before it has actually been reduced to practice." As stated in the written description guidelines "an applicant shows possession of the claimed invention by describing the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways, including...by describing distinguishing identifying characteristics sufficient to show that the

applicant was in possession of the claimed invention." 1255 Official Gazette 140 (Feb. 5, 2002). Pedigree, which is a formula used by plant breeders, is a distinguishing identifying characteristic in compliance with the written description guidelines. Further, the Examiner must evaluate written description by the claimed invention with all of its limitations, including the limitation of being derived from PH54M.

PH54M-derived progeny are described by the fact that PH54M is utilized in a breeding program to make the PH54M-derived progeny, PH54M gives genetic contribution to the PH54M-derived progeny, and the genetics of PH54M are described by ATCC deposit of PH54M seed. By limiting the progeny to 2 or less crosses away from PH54M, the Examiner's concern that the progeny may be only distantly related to PH54M is addressed. In Enzo vs. Gen-Probe, U.S. State Court of Appeals for the Federal Circuit, 63 USPQ 2d 1609, the court reversed its prior decision regarding the insufficiency of the deposited genetic probes to meet the written description requirement. In so holding, the court stated, " As the deposited sequences are about 850, 8500, and 1300 nucleotides long, ..., there are at least hundreds of subsequences of the deposited sequences, an unknown number of which might also meet the claimed hybridization ratio. Moreover, Enzo's expert, Dr. Wetmur, stated that 'astronomical' numbers of mutated variations of the deposited sequence also fall within the scope of those claims, and that such broad claim scope is necessary to adequately protect Enzo's invention from copyists who could otherwise make minor change to the sequence and thereby avoid infringement while still exploiting the benefits of Enzo's invention. The defendants assert that such breadth is fatal to the adequacy of the written description. On the other hand, because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art. We regard that question as an issue of fact...."

The issue of whether the progeny as now claimed satisfies the written description requirement is also an issue of fact. One of ordinary skill in the art

would know if PH54M were utilized in a breeding program by looking at the breeding records and therefore would know if a progeny were derived from PH54M. PH54M is a unique inbred, as evidenced by the morphological and physiological traits given in Table 1, pages 18-20, of the application. Routinely used molecular techniques, discussed on page 16, lines 8-23 of the application, can be used to verify whether PH54M is within the pedigree of a line.

Applicant would also like to emphasize that PH54M cannot be derived through any other means then through PH54M seed and plant, nor can the influence of PH54M on the progeny be removed from a line within 2 outcrosses of PH54M. This fact also highlights the different perspective between the Examiner and the Applicant regarding the scope of the claims. The Examiner believes the claims to progeny to be of great breadth. However, to view these claims as being of great breadth merely because a large number of plants could theoretically fall within its scope ignores an essential limitation of the claim; that only a plant developed through the use of PH54M is within the scope of the claim. Such a plant could not be independently derived without the use of PH54M, so the claim would not in any way restrict the work of a breeder that did not in fact use PH54M. A breeder infringing such a claim must have made a conscious choice to use PH54M in order to obtain some or all of PH54M's desired characteristics. Compliance with the written description requirement is essentially a fact based inquiry that will "necessarily vary depending on the nature of the invention claimed." Vas-Cath v. Mahurkar, 935 F. 2d 1555 (citing In re DiLeone, 436 F2d. 1404, 1405). Thus, the compliance with the written description requirement must be judged in view of this limited scope of the progeny claims. As amended, the claims are drawn to only a limited scope of progeny, progeny which but for Applicant's creation of PH54M could never have existed. This is in harmony with the statement in section 2163 of the MPEP that "the written description requirement promotes the progress of the useful arts by ensuring inventions are adequately described in the specification in exchange for the right to exclude." That quid pro quo of patent law has been met by the Applicant in the present case, and to use written description to deny adequate

patent protection would be contrary to the stated purpose of the written description requirement.

The Examiner goes on to reject claims to PH54M plants further containing transgenes and single gene conversions under 35 U.S.C.112, first paragraph. Applicant notes that examples of traits and single gene conversions are given in the specification, page 23, line 20 through page 33 line 4. Even if more than one trait is affected by the transgene, the genetics of PH54M will be only minimally affected. The Examiner must consider all limitations of the claimed invention. While the Examiner is focusing on traits, the Applicant points out that they are not claiming so broadly as to claim any maize plant, regardless of source, comprising those traits. The Applicant is claiming PH54M, or a limited set of plants derived therefrom, that retain significant features of PH54M. The Applicant has made an enabling deposit of PH54M with the ATCC, and the Applicant is seeking a fair scope of protection as the quid pro quo for the teaching in the specification and the deposit of the material. The insertion of one or a few genes into a genome that is estimated to have over 50,000 to 80,000 genes (Xiaowu, Gai et al., Nucleic Acids Research, 2000, Vol. 28, No. 1, 94-96) is a minor change to PH54M and will not prevent one of skill in the art from identifying the plant as PH54M. In addition, to expedite prosecution, Applicant has amended claim 11. Claim 11 now reads, "The maize plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes that confer a qualitative trait." Qualitative traits, as described in an introductory plant breeding book, are traits that "have phenotypes that can be divided into discrete classes...They are controlled by one or a few major genes whose expression is not influenced markedly by the environment" (Fehr, W., Principles of Cultivar Development, vol.1, 1987, page 26). Claim 30 has been cancelled. The Examiner has suggested that claims 11 and 30 be amended to list the types of transgenes contemplated in the specification, for example disease or pest resistance genes, provided the prior art teaches those isolated genes. The Applicant believes that an amendment as suggested by the Examiner is limiting the scope to which the

Applicant is entitled. Examples of specific transgenes are given in the specification and one of ordinary skill in the art would be able to determine additional transgenes that may be used. The Examiner states that, "Transgenes may also be of any gene, including those that effect more than one trait. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from PH54M, which are not described." Applicant points out that the molecular profile of such a plant would be substantially unchanged and therefore one would be able to identify such a plant. The Applicant has amended claim 11 with traverse in order to expedite allowance.

The Examiner rejects claims 12, 13, 31, and 32. Claims 12 and 31 are drawn to the method of crossing a PH54M plant containing a transgene with another plant. Claim 13 and 32 are to the plant made from the method. Claims 31 and 32 have been cancelled. Claims 12 and 13 have been amended for clarification purposes. Applicant points out that the methods are fully described. Furthermore, one of ordinary skill in the art would know if they were using or one could easily identify if they were using PH54M or PH54M further containing a transgene to develop a hybrid. All F1 plants would comprise essentially the same genetic markers as the deposited PH54M. It is well known to anyone skilled in the art that a hybrid has a genome with one set of the alleles from each inbred. Therefore the genetic profile exhibited in the deposit would be exhibited in the hybrid. The plant of claim 13 would have the genetic profile of PH54M except at the site of integration of the transgene. The change of one to a few genes out of an estimated 50,000 to 80,000 genes is a minor change and will not prevent one of ordinary skill in the art from identifying the plant as PH54M. One of ordinary skill in the art would also know how to cross PH54M containing a transgene with another plant to produce a hybrid. Thus, the Applicant has described the invention with sufficient specificity to enable others to make and use the invention. In light of the arguments and amendments, the Applicant requests that the Examiner withdraw his rejection to claims 12 and 13.

The Examiner also rejects claims 37-39 under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the application was filed, had possession of the claimed invention. Claims 37-39 are clearly directed to growing out an F(1) hybrid in which PH54M is a parent and searching for PH54M inbred seed. Due to the imperfect process of seed production parent seed can sometimes be contained in the hybrid seed bag. The claims merely claim the method of searching for inbred PH54M seed within a bag of hybrid seed. The method is also clearly described in the specification on page 5, line 21 through line 10 on page 6. The Applicant requests that the Examiner withdraw his rejection to claims 37-39.

Lastly, The Examiner has rejected certain method claims under written description. Applicant points out that the methods are fully described, as is the starting material in the method, PH54M. One of ordinary skill in the art would know how to cross PH54M to develop an F1 hybrid and also how to self plants derived from crosses with PH54M for the purpose of developing an inbred plant. In *Ex parte Parks*, 30 USPQ 2d 1234 (B.P.A.I. 1994), the Board of Appeals stated, "Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." Emphasis added. In *J.E.M. Ag. Supply*, the Supreme Court also acknowledged the value of a newly developed line in further breeding, when it stated that, "...a breeder can use a plant that is protected by PVP certificate to 'develop' a new inbred line while he cannot use a plant patented under §101 for such a purpose." Id. at 1873. In light of the amendments to the claims and the foregoing arguments the Applicant requests reconsideration of the rejection under the first paragraph of 35 U.S.C. 112.

5. The Examiner rejects claims 18-20 and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant traverses the rejection.

The Examiner rejects claims 18-20 and 47-49 that are directed to PH54M inbred maize plant further comprising one or more single gene conversions. Claims 18 and 47 are directed to PH54M that contains a gene that has been transferred to PH54M through traditional breeding methods. The claims have been amended to expedite prosecution. Claim 18 now reads, "The maize plant, or parts thereof, of claim 2, further comprising one or more genes that confer a qualitative trait and have been transferred into said maize plant through breeding methods that utilize PH54M as a recurrent parent." Claim 47 now reads, "The maize plant, or parts thereof, of claim 2, further comprising one or more genes that have been transferred into said maize plant by utilizing PH54M as a recurrent parent and wherein the maize plant, or parts thereof, are essentially unchanged from inbred maize line PH54M." New claims 50, 51, 52, and 53 have been added and are also directed to plants wherein traits have been backcrossed in to PH54M and the method of backcrossing traits into PH54M. These claims include lists of traits. Once again the Applicant would like to point out that one of ordinary skill in the art would be able to detect a PH54M maize plant that contains genes that have been inserted through crossing. The genetics would be substantially the same as PH54M as would the morphological and physiological traits of PH54M. The specification states, "A further embodiment of the invention is a single gene conversion or introgression of the maize plant disclosed herein in which the gene or genes of interest (encoding the desired trait) are introduced through traditional (non-transformation) breeding techniques, such as backcrossing (Hallauer *et al,* 1988)."

The Examiner has cited articles and states that they "teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic

background of a different plant, to confer a desired phenotype in said different plant." The Examiner states that, "Hunsperger et al. teach that the introgession of a gene in one genetic background on any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). " This is not what is taught by Hunsperger et al. Hunsperger et al. teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger et al. merely discusses the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger et al. succeeded in incorporating the gene into petunia plants of different genetic backgrounds. Therefore Hunsperger et al. demonstrate that one of ordinary skill in the art can use traditional breeding methods to obtain maize plants containing genes that confer a qualitative trait. The specification provides ample disclosure of starting materials such as maize inbred PH54M, a discussion of traditional breeding methods that may be used, and examples of transgenes and naturally occurring genes. Please note in Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, it states that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage."

The Examiner goes on to state that, "Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-dependent in nature (page 323, column 1, lines 7-15)." Applicant disagrees that the article states such points. Applicant assumes that the Examiner is trying to point out that one gene cannot be introduced into a plant using traditional breeding techniques such as backcrossing without also Introducing closely linked genes into the plant. It is well understood in the relevant art that DNA surrounding the gene of the desired trait is introduced into the plant when traditional breeding techniques are utilized to insert a gene into a plant of interest. It is also understood in the art that introducing a gene into a

plant variety such as PH54M is an insubstantial change to the variety. The World Seed Organization, on it's web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering. The commercialization of an essentially derived variety needs the authorization of the owner on the rights vested in the initial variety." International Convention for the Protection of New Varieties of Plants, as amended on March 19, 1991, Chapter V, Article 14, Section 5(c), (emphasis added). A copy of the relevant portion of the UPOV Convention and the World Seed Organization web site is attached as Appendix C.

An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. Poehlman et al. (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross."

The Examiner goes on to state that, "Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may effect quantitative traits in genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). The Applicant would like to first point out on page 1816, column 1, lines 1-5 of the Eshed et al. article it states, "Recent studies that detected epistasis of s lected QTL in Drosophila (Long et al. 1995), soybean (Lark et al.1995) and maize (Doebley et al.1995; Cockerham and Zeng 1996) did not show a less-than-additive trend." Emphasis added. Applicant also adds that

transferring a qualitative trait does not require undue experimentation. Please note Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." As stated previously claims 18 and 47 have been amended to expedite prosecution. In claim 18, the genes transferred into PH54M are now limited to qualitative traits. Claim 47 is now limited to plants that are essentially unchanged from PH54M. Given the arguments and the amendments the Applicant requests reexamination and reconsideration of the claims.

As noted in the specification, the development of an inbred line is a time consuming and labor intensive activity. On average, between 10,000 to 20,000 lines are created and screened in order to develop any maize inbred line for which the Applicant files a patent application. Once developed, the inbred line is useful for two purposes: (1) to make commercial hybrids, and (2) as a source of breeding material for the development of new inbreds that retain the original inbred's desired characteristics. A breeder desiring to make a line with similar traits to PH54M would be greatly advantaged by being able to use PH54M as starting material. This is because the linked genes arranged through Applicant's breeding efforts, and fixed in PH54M, can be maintained in the progeny of PH54M by a breeder of ordinary skill in the art. For example, if a breeder of ordinary skill in the art desired a waxy-kernel corn version of PH54M, the breeder could cross PH54M to a waxy-kernel corn variety, select for progeny with the desirable traits of PH54M that also express the waxy kernel trait, and continue selecting for the traits of PH54M combined with waxy kernels. Optionally, the breeder could backcross to PH54M to obtain further genetic contribution from PH54M. The end result is the development of an inbred line with substantially all of the benefit of Applicant's work but with only a fraction of the effort.

6. The Examiner rejects claims 1-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most

nearly connected, to make and/or use the invention. The Examiner states that the seeds must be readily available to the public. The Applicant has deposited the seed of PH54M with the ATCC and has amended the claims accordingly. A receipt of the deposit is attached. The deposit and amendment to the claims obviate the rejection.

In light of the amendments to the claims and the foregoing arguments the Applicant requests reconsideration of the rejection under the first paragraph of 35 U.S.C. 112.

Claim Rejections under 35 U.S.C. § 102 and 103

7. Examiner states that, "Claims 1-49 are rejected under 35 U.S.C. 102(b) as anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Loisel (U.S. Patent No. 5,986,185). " Applicant traverses the rejection.

The Examiner goes on to state, "Loisel teaches seed of an inbred maize line designated 'PH24D', plants produced by growing said seed, and plants and plant parts having all the physiological and morphological characteristics of PH24D (col. 10, lines 52-67; Table 1; claims). It appears that the claimed plants and seeds of the instant invention may be the same as PH24D, given that they exhibit similar traits, high grain yield, above average resistance to Northern Leaf Blight, and being adapted to the Northcentral region of the United States, for example (col. 10, lines 59-67; Table 1). Alternatively, if the claimed plants, plant parts, and seeds of PH54M are not identical to PH24D, then it appears that PH24D only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer patentable distinction to PH54M."

Applicant points out that the designation "PH54M" of the instantly claimed cultivar is not arbitrarily assigned. PH54M seed has been deposited with the ATCC and the specification and the appropriate claims have been amended to include the ATCC deposit number. The Applicant also points out that the

differences between PH54M and PH24D are not "minor morphological variations". On page 17, lines 4-6 of the specification it states that PH54M is used to produce hybrids with a 98 Comparative Relative Maturity Rating. In column 10, lines 54-59 of the Loisel patent it states that PH24D is a maize inbred that is used to produce hybrids that have a relative maturity of approximately 87. Other differences are taken from Table 1 of the specification, pages 18-20, and Table 1 of the Loisel patent, columns 11-16 and are listed in the following table.

PH54M	PH24D
Dent	Flint
67 days from emergence to 50% plants in silk	69 days from emergence to 50% plants in silk
68 days from emergence to 50% plants in pollen	70 days from emergence to 50% plants in pollen
1,228 heat units from emergence to 50% plants in silk	1,175 heat units from emergence to 50% plants in silk
1,251 heat units from emergence to 50% plants in pollen	1,218 heat units from emergence to 50% plants in pollen
Cob color is red	Cob color is white
Silk color is light green	Silk color is red
7 = Eye spot resistance score	5 = Eye spot resistance score
4,555 Kg/ha yield	3,206 Kg/ha yield

The examples and the list are not exhaustive but they give ample evidence that the inventions are not the same. Nor are they minor variations of each other.

Applicant has canceled claims 44, 45 and 46. Applicant has amended claims 14, 40, 41, 42, and 43. Claim 41 has been amended and now reads, " A first generation (F1) PH54M-progeny maize plant, or parts thereof, produced by the method of claim 40." Claim 41 is now one cross away from PH54M. Claim 41 clearly states that PH54M must be used to obtain a PH54M-progeny maize plant. Claim 42 has been amended so that it does not allow any further crosses away from PH54M. Thus claim 42 is the selfing of the plant derived by the one cross away from PH54M made in claim 40. Claim 43 has been amended for clarification purposes. These PH54M-progeny plants are limited to one cross away from PH54M and the progeny plants are limited by the use of PH54M in the initial cross. Applicant contends that progeny of PH54M could not the same as PH24D or the progeny of PH24D because PH54M is not PH24D. One would not be able to obtain plants within one cross of PH54M through modification of the maize inbred PH24D taught in U.S. Patent No. 5,986,185 because PH54M

comprises a unique and nonobvious combination of genetics. As evidenced by past arguments and the declaration of Stephen Smith submitted as Appendix D, the claimed progeny plants of PH54M retain unique and nonobvious combinations of genetics derived from PH54M. Thus, they deserve to be considered new compositions in their own right.

In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to claims 1-49 under 35 U.S.C. 102 (b) and 103(a).

Cancellation of claims 30, 31, 32, 44, 45, and 46; amendment of claims 1, 3, 4, 6, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 27, 33, 34, 35, 36, 37, 40, 41, 42, 43, 47, 48, and 49; and addition of claims 50-53 does not in any way change the claim scope which the Applicant believes is allowable but is meant to hasten the issuance of the patent.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

Applicant submits that in light of the foregoing amendments and the remarks, the claims 1-29, 33-43, and 47-53 are in condition for allowance. Reconsideration and early notice of allowability is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specifications

At page 57, following "Deposits", the entire paragraph, lines 2-21, were deleted and the clean paragraph as written was inserted.

In the Claims

Claims 30, 31, 32, 44, 45 and 46 were cancelled.

Claims 1, 3, 4, 6, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 27, 33, 34, 35, 36, 37, 40, 41, 42, 43, 47, 48 and 49 were amended as follows.

1. (Amended) Seed of maize inbred line designated PH54M, representative seed of said line having been deposited under ATCC Accession No.[_____] PTA-4527.

3. (Amended) The maize plant of claim 2, wherein said plant is [male sterile] detasseled.

4. (Amended) A tissue culture of regenerable cells or protoplasts from the plant of claim 2.

6. (Amended) A maize plant regenerated from the tissue culture of claim 4, capable of expressing all the morphological and physiological characteristics of inbred line PH54M, representative seed of which have been deposited under ATCC Accession No.[_____] PTA-4527.

8. (Amended) The method of claim 7 wherein the plant of inbred maize line PH54M [plant of claim 2] is the female or male parent.

11. (Amended) The maize plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes [operably linked to one or more regulatory elements] that confer a qualitative trait.

12. (Amended) A method for producing a first generation (F1) maize plant [that contains in its genetic material one or more transgenes,] comprising crossing the maize plant of claim 11 with [either] a second plant [of another maize line, or a non-transformed maize plant of the line PH54M, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element].

13. (Amended) [Maize plants] The first generation (F1) maize plant, or parts thereof, produced by the method of claim 12.

14. (Amended) A maize plant, or parts thereof, wherein at least one ancestor of said maize plant is the maize plant of claim 2, said maize plant expressing a combination of at least two PH54M traits which are not significantly different from PH54M traits when determined at a 5% significance level and when grown in the same environmental conditions, said PH54M traits selected from the group consisting of: a relative maturity of [approximately] 98 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, [high] grain yield, [above average] resistance to late season stalk lodging, and [above average] resistance to Northern Leaf Blight[, and adapted to the Northcentral region of the United States].

15. (Amended) A method for developing a PH54M-progeny maize plant in a maize plant breeding program using plant breeding techniques, which include employing a maize plant, or its parts, as a source of plant breeding material, comprising: obtaining the maize plant, or its parts, of claim 2 as a source of said breeding material.

16. (Amended) The [maize plant breeding program] method of claim 15 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

17. (Amended) [A] The PH54M-progeny maize plant, or parts thereof, produced by the method of claim 15 wherein the method comprises 2 or less crosses to a plant other than PH54M or a plant that has PH54M as a parent.

18. (Amended) The maize [plants] plant, or parts thereof, of claim 2, further comprising one or more [single gene conversions] genes that confer a qualitative trait and have been transferred into said maize plant through breeding methods that utilize PH54M as a recurrent parent.

19. (Amended) The [single gene conversion(s)] maize plant of claim 18, wherein [the gene] at least one of the genes is a dominant allele.

20. (Amended) The [single gene conversion(s)] maize plant of claim 18, wherein [the gene] at least one of the genes is a recessive allele.

21. (Amended) A maize plant, or parts thereof, having all the physiological and morphological characteristics of inbred line PH54M, representative seed of said line having been deposited under ATCC Accession No. [_____] PTA-4527.

22. (Amended) The maize plant of claim [21] 2, wherein [said plant is male sterile] genes controlling male sterility have been transferred into said maize plant through crossing, wherein PH54M is a recurrent parent, and wherein said plant has essentially the same morphology and physiology of inbred maize line PH54M other than the trait of male sterility.

23. (Amended) A tissue culture of regenerable cells or protoplasts from the plant of claim 21.

25. (Amended) A maize plant regenerated from the tissue culture of claim 23, capable of expressing all the morphological and physiological characteristics of inbred line PH54M, representative seed of which have been deposited under ATCC Accession No. [_____] PTA-4527.

27. (Amended) The method of claim 26 wherein the inbred maize plant [of claim 21] having all the morphological and physiological characteristics of inbred maize plant PH54M is the female or male parent.

33. (Amended) A PH54M-progeny maize plant, or parts thereof, wherein at least one ancestor of said PH54M-progeny maize plant is the maize plant of claim [21] 2, [said maize plant expressing a combination of at least two PH54M traits selected from the group consisting of: a relative maturity of approximately 98 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, high grain yield, above average resistance to late season stalk lodging, above average resistance to Northern Leaf Blight, and adapted to the Northcentral region of the United States] and wherein the pedigree of said PH54M-progeny maize plant is within 2 or less crosses to a plant other than PH54M or a plant that has PH54M as a parent.

34. (Amended) A method for developing a PH54M-progeny maize plant in a maize plant breeding program using plant breeding techniques, which include employing a maize plant, or its parts, as a source of plant breeding material, comprising: obtaining the maize plant, or its parts, of claim 21 as a source of said breeding material.

35. (Amended) The [maize plant breeding program] method of claim 34 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

36. (Amended) [A] The PH54M-progeny maize plant, or parts thereof, produced by the method of claim 34 wherein the method comprises 2 or less crosses to a plant other than PH54M or a plant that has PH54M as a parent.

37. (Amended) A process for producing inbred PH54M, representative seed of which have been deposited under ATCC Accession No. [_____] PTA-4527, comprising:

(a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred PH54M said collection also comprising seed of said inbred;

(b) growing plants from said collection of seed;

(c) identifying said inbred PH54M plants;

(d) selecting said inbred PH54M plant; and

(e) controlling pollination in a manner which preserves the homozygosity of said inbred PH54M plant.

40. (Amended) A method for producing a first generation (F1) PH54M-[derived] progeny maize plant, comprising:

(a) crossing inbred maize line PH54M, representative seed of said line having been deposited under ATCC Accession No. [_____] PTA-4527, with a second maize plant to yield progeny maize seed;

(b) growing said progeny maize seed, under plant growth conditions, to yield said first generation PH54M-[deriv d] progeny maize plant.

41. (Amended) A first generation (F1) PH54M-[derived] progeny maize plant, or parts thereof, produced by the method of claim 40[, said PH54M-derived maize plant expressing a combination of at least two PH54M traits selected from the group consisting of : a relative maturity of approximately 98 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, high grain yield, above average resistance to late season stalk lodging, above average resistance to Northern Leaf Blight, and adapted to the Northcentral region of the United States].

42. (Amended) [The] A method for producing a PH54M progeny inbred maize plant, comprising generating the first generation (F1) PH54M-progeny maize plant by the method of claim 40[,] and further comprising:

[(c) crossing said PH54M-derived maize plant with itself or another maize plant to yield additional PH54M-derived progeny maize seed;

(d) growing said progeny maize seed of step (c) under plant growth conditions, to yield additional PH54M-derived maize plants;

(e) repeating the crossing and growing steps of (c) and (d) from 0 to 5 times to generate further PH54M-derived maize plants] selfing said first generation (F1) PH54M-progeny maize plant for successive filial generations to generate a PH54M inbred progeny maize plant.

43. (Amended) [A further derived] The PH54M inbred progeny maize plant, or parts thereof, produced by the method of claim 42.

47. (Amended) The maize [plants] plant, or parts thereof, of claim [21] 2, further comprising one or more [single gene conversions] genes that have been transferred into said maiz plant by utilizing PH54M as a recurrent parent and wherein the maize plant, or parts thereof, are essentially unchanged from inbred maize line PH54M.

48. (Amended) The [single gene conversion(s)] maize plant of claim 47, wherein [the gene] at least one of the genes is a dominant allele.

49. (Amended) The [single gene conversion(s)] maize plant of claim 47, wherein [the gene] at least one of the genes is a recessive allele.

New claims 50, 51, 52, and 53 were added.